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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/823,073

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Michael G. Lowery

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EXAMINER

BERHANU, ETSUB D

ART UNIT

PAPER NUMBER

3768

MAIL DATE

DELIVERY MODE

06/09/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/823,073	Applicant(s) LOWERY, MICHAEL G.	
	Examiner ETSUB D. BERHANU	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 22 April 2010 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-10 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites the limitation "wherein the predetermined amount of the layer of coupling agent is an appropriate amount for enhancing optical and thermal coupling between the tissue or the body part and a separate measuring device including an optical probe." The phrase "an appropriate amount" renders the claim indefinite as it is unclear what amount of coupling agent is considered an appropriate amount and what amount of coupling agent is not considered an appropriate amount.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Atkinson et al.'471 (USPN 5,409,471 – previously cited).

Figure 1 of Atkinson et al.'471 discloses an article 10 comprising a backing and having a layer of silicone oil (a coupling agent) over at least one major surface of the backing (col. 2, lines 45-60). While the article of Atkinson et al.'471 is used to apply a coating of alcohol and silicone oil onto a medical coupling site (col. 3, lines 18-23), the article of Atkinson et al.'471 is capable of uniformly and useably transferring an amount of silicone oil to a tissue or body part when the article is applied to a tissue or body part and then removed. Furthermore, any amount of silicone oil transferred to the tissue or body part would enhance optical and thermal coupling between the tissue or body part and a separate device including an optical probe when compared to a coupling between the tissue or the body part and a separate measuring device with no coupling agent present.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Atkinson et al.'471.

Atkinson et al.'471 discloses all the elements of the current invention, as discussed in paragraph 5 above, except for the size of the layer of coupling agent and the size of the backing. Regarding claims 4-7, as the Applicant has failed to provide criticality or unexpected results for the values of sizes recited in claims 4-7, it would have been within the skill of the art, through due experimentation, to realize an

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optimum thickness for the coupling agent layer and an optimum area of the backing, in order to provide the most accurate results.

8. Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Messerschmidt'951 (USPN 5,823,951 – previously cited) further in view of Follis'279 (USPN 6,045,279 – previously cited).

Messerschmidt'951 discloses a method for analyzing glucose (col. 1, lines 11-13), the method comprising: applying a coupling agent to a tissue, bringing an optical measuring device in contact with the coupling agent and tissue and performing a non-invasive determination of glucose in the tissue through localized reflectance measurements (col. 11, line 47 – col. 12, line 18). Messerschmidt'951 discloses all the elements of the current invention, as discussed above, except for the method in which the coupling agent is applied to the tissue. Follis'279 teaches the use of an article to uniformly apply a fluid substance to a tissue site. Figure 1 of Follis'279 discloses an article 10, while Figure 2 of Follis'279 discloses that the article comprises a backing layer 54, that, when in use, comprises a uniform fluid substance layer 16 over the backing layer. The article is placed in contact with the tissue and when the article is removed from the tissue, a uniform layer of the fluid substance is useably transferred to the surface of the tissue (col. 3, line 39 – col. 4, line 37). It would have been within the skill of the art to implement the article and method of Follis'279 with the method of Messerschmidt'951 since Messerschmidt'951 requires a fluid coupling agent to be applied to the tissue, but fails to disclose details of how the coupling agent is applied to the tissue, and Follis'279 provides details of a means and method of applying a fluid substance to a tissue that is capable of being used in the method of Messerschmidt'951.

Response to Arguments

9. Applicant's arguments, see pages 5-6 of the Remarks, filed 22 April 2010, with respect to the rejection of claims 1-10 and 15 in view of Delonzor have been fully considered and are persuasive. The

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rejection of claims 1-10 and 15 in view of Delonzor has been withdrawn. However, upon further consideration, a new ground(s) of rejection has been made in view of Atkinson as discussed in paragraph 5 above. Applicant's arguments on pages 7-8 of the Remarks with respect to the rejection of claims 11-14 in view of the combination of Messerschmidt and Follis has been fully considered but they are not persuasive. Applicant argues that Follis does not disclose or suggest an article comprising a layer of fluid that provides a surface on the article for contacting the tissue or body part. As discussed in paragraph 10 above, when used in the method of Messerschmidt further in view of Follis, the article of Follis comprises a layer of coupling agent over a surface of a backing, the coupling agent providing a surface on the article for contacting the tissue or body part. Pressure is applied to the chamber of Follis, causing the coupling agent to flow to the surface of backing layer 54. The article is then placed on the body part, wherein the coupling agent makes contact with the body part, and the article is used to uniformly distribute the coupling agent to the body part before it the article is removed from the body part. For these reasons, the Applicant's arguments are not persuasive.

Allowable Subject Matter

10. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art teaches or suggests, either alone or in combination, an article for applying a coupling agent to a surface of a tissue or a body part wherein the article comprises either: a backing comprising a non-permeable material, or a substrate layer between the backing and a layer of the coupling agent, in combination with the other claimed elements.

11. Claims 3 and 8-10 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ETSUB D. BERHANU whose telephone number is (571)272-6563. The examiner can normally be reached on Monday - Friday (7:00 - 3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

EDB

/Etsub D Berhanu/
Examiner, Art Unit 3768